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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,230	05/17/2002	Naresh Kumar	RLL-159US	5863

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EXAMINER	
CHANG, CELIA C	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 04/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,230	KUMAR ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *09 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment and response filed by applicants in paper No. 11, dated Dec. 9, 2003 have been entered and considered carefully. Claims 1-13 and newly added claims 14-17 are pending.

2. The rejection of claim 1 under 35 USC 102(b) over Coutant et al. is dropped over claim 1 but maintained over claims 15-17. Please note that the method of treating a condition which fexofenadine hydrochloride is indicated is exactly how such blood fexofenadine of Coutant is doing. Therefore anticipation was found.

In addition these newly added claims 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is the term "a condition which fexofenadine hydrochloride is indicated". Is it a disease? Is it a physical phenomenon? What exactly is this term intended? Clarification is required. To the extend that this term is referring to a disease or pathology in a subject the above 102(b) is proper. To the extend that this term is referring to some condition wherein only a hydrochloride of fexofenadine is treatable but not fexofenadine, then the following 112 first paragraph rejection is applicable.

Claims 15-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Please note that the term "a condition for which fexofenadine hydrochloride is indicated" lacks antecedent basis in the specification as well as enablement. Please note that the acid addition salt of a "drug" is a pharmaceutical formulation for drug delivery (see Berge of record). The acid addition salt is therefore dependent on the parent "drug" for therapeutic utility. Were the term is intended for conditions wherein only a hydrochloride of fexofenadine is treatable but not fexofenadine, then the specification lacks description and enabling support and is considered NEW MATTER.

Removal of all new matter is required. In re Ressmussen 211 USPQ 352.

3. The rejection of claim 1 over Meiwes et al. '127 in view of Berge is maintained for reason of record.

Applicants argued that Berge disclosed many salts and choosing the particular salt is not suggested. Please note that, one given the known FDA approved salts would not have to judicially pick and choose especially as pointed out by applicants Berge disclosed that such picking and choosing are empirical and many factor such as cost, yield can be considered. Therefore, with such clear guidance there is no difficulty in choosing or making salts. Since hydrochloride is the very popular and reasonably priced FDA approved salt, applicants offer no rational as to why one skilled in the art would not choose such to prepare salt of Meiwes' drug in formulation.

4. The rejection of claims 1-13 under 35 USC 103(a) over Carr '129 or WO 95/31437 or Woosley '693 in view of Lieberman, Susukin, Corrigan, Nuernberg and Sato supplemented with '127 which is also applicable to newly added claims 14-17 is maintained for reason of record.

Applicants argued that the primary references of Carr '129, WO '437 or Woosley '693 disclosed crystalline fexofenadine. The isolate the difference of Lieberman, Susukin, Corrigan, Nuernber and Sato or '127 individually. It was clearly delineated that Lieberman, Susukin, Corrigan, Nuernber and Sato or '127 collectively showed the state of the pharmaceutical art that such skill as freeze drying, spray drying are conventional size reduction processes for one skilled in the art to prepare amorphous substance which as suggested by these art to enhance drug dissolution thus bioavailability. Such dissection of the teaching of the art by attaching references individually where as a whole indicated per ponderous of evidence of the state of the art cannot obviate the obviousness as established by the combination of references. In re Keller 208 USPQ 871. Applicants provided no "factual evidence" why one in possession of the solid form of fexofenadine hydrochloride in Carr '129 or WO '437 or Woosley '693 knowing and enabled by the well recognized freeze drying or spray drying procedure to produce a product better "bioavailable" would not employ such conventional process for such product which will be amorphous fexofenadine hydrochloride i.e. the claims.

5. The provisional rejection of claims 1-13 which is now also applicable to claims 14-17 under 35 USC 102(f), (g) or (e) over US 2002/01776608 or WO 02/066429 is maintained for reason of record.

Applicants alleged that swear behind can be submitted without submission.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Mar. 25,2004

Celia Chang
Primary Examiner
Art Unit 1625